REMARKS

Pursuant to the entry of this amendment, claims 1-24 are pending in this application, with claims 6-19 being withdrawn from consideration subject to a restriction requirement. Accordingly, claims 1-5 and 20-24 are presently under consideration. Regarding the specific amendments to the claims:

Claim 1 has been amended to clarify that the lipid fraction comprises a *Nigella sativa* oily lipid fraction composed of about 73 to about 92% by weight polyunsaturated fatty acids that is free of *Nigella sativa* L solid fats. Support for this amendment is found in the specification as originally filed, particularly at p. 4, lines 4-5 ("The polyunsaturated fatty acid fraction is present in an amount of about 73 to about 92% by weight (preferably about 84% by weight) in the total fatty acid fraction."), p. 2, lines 16-19 ("The lipid fraction is extracted from the seeds of *Nigella sativa* L in a manner that yields an oily fraction that is comprised primarily of long chain fatty acids, volatile oils and sterols and that is free from *Nigella sativa* L solid fats, including, for example, waxes, resins, tocopherols, triterpenes, aglycons, short chain fatty acids, and hydrocarbons.") and Figure 1 ("Cooling separates the fat (solid) fraction from the Lipid (Oil) Fraction."). Applicant respectfully submits that the claims so amended define a composition distinct from that found in the prior art. Applicant further submits that no new matter has been added.

Accordingly, Applicant submits that the instant response renders moot the outstanding claim rejections and places the instant application in condition for allowance. Further to this position, Applicants submit the following remarks:

Rejections under 35 USC § 112, First Paragraph

Claims 1-5 and 20-24 stand rejected under 35 U.S.C. § 112, First Paragraph, as failing to comply with the written description requirement. According to the Examiner, "[a]lthough the disclosure teaches that the lipid fraction is primarily composed of long chain fatty acids, sterols, and volatile oils, it cannot be found wherein the lipid fraction is primarily composed of linoleic, oleic, and linoleic acid." Thus, the Examiner characterizes the limitation as "new matter".

Applicant respectfully disagrees and again refers the Examiner to page 4, lines 4-17 and Table 1 on page 5, the relevant parts of which are reiterated below:

> "The polyunsaturated fatty acid fraction is present in an amount of about **73 to about 92% by weight (preferably about 84% by weight)** in the total fatty acid fraction. . . . In the total fatty acid fraction, the *Nigella sativa* L. polyunsaturated fatty acid fraction comprises **about 51 to about 61% by weight octadecadienoic acid** (i.e., substantially in the form of cis-9,12-octadecadienoic acid (i.e., **linoleic acid**)); **about 20 to about 25% by weight octadecenoic acid** (i.e., substantially in the form of cis-9-octadecenoic acid (i.e., **oleic acid**)); about **0.7 to about 2% by weight cis-9,12,15-octadecatrienoic acid** (i.e., **linolenic acid**); cis-11,14-eicosadienoic acid (preferably in an amount of about 1 to about 2.6% by weight); cis-9-tetradecenoic (i.e., myristoleic acid) (preferably in an amount of about 0.10 to about 0.21% by weight); and cis-9-hexadecenoic (i.e., palmitoleic acid) (preferably in an amount of about 0.30 to about 1.0% by weight), as shown in Table 1 below." (page 4, lines 4-17, emphasis added)

As noted in Table 1, linoleic, oleic, and linoleic acid are all C18 polyunsaturated fatty acids. Accordingly, Applicant respectfully submits that the specification as originally filed supports the assertion that the lipid fraction is composed primarily of C18 polyunsaturated fatty acids. Nevertheless, in an effort to expedite prosecution, Applicants have amended claim 1 to specify that the lipid fraction comprises "about 73 to about 92% by weight polyunsaturated fatty acids". Applicant submits that the specification as originally filed provides explicit support for this limitation. As such, Applicant respectfully requests reconsideration and withdrawal of the new matter rejection in view of the amendments and remarks herein.

Rejections under Section 102(b) - Ramadan and Morsel:

Claims 1, 2, 3, 23, and 24 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Ramadan and Morsel (Nahrung/Food 2002). According to the Examiner, Ramadan and Morsel describe a *Nigella sativa* fixed oil prepared by hexane extraction that contains approximately 60% linoleic acid and approximately 20% oleic acid. The Examiner further asserts that Ramadan and Morsel disclose the study of the "*in-vivo* toxicity of *Nigella sativa*

fixed oil prepared by hexane extraction on *lops ofsa* mice, wherein one group received the *Nigella sativa* fixed oil mixed with gum acacia (considered a pharmaceutical carrier) (see for example, pp. 240-241, Experimental, p. 241, and table 2, p. 242)." The Examiner thus concludes that the mixture of 5% acacia and *Nigella sativa* oil, allegedly described by Ramadan and Morsel could be used as an ointment or balm and therefore anticipates the invention of the pending claims.

Applicant respectfully disagrees.

In order to anticipate a claim, a single reference must disclose each and every element of the claim. In this case, contrary to the Examiner's suggestion, Ramadan and Morsel (Nahrung/Food 2002) includes no reference to either *in vivo* toxicity studies or pharmaceutical compositions comprised of 5% acacia and *Nigella sativa* oil. In fact, the entirety of the Ramadan and Morsel disclosure is directed to the experimental characterization of the content and composition of a pure seed oil extracted from *Nigella sativa*, focusing with particularity on the phospholipids (PL) contained therein and "the potential economic utility of *Nigella sativa* L. seed oil as a new source of PL." (see p. 243, col. 2). Thus, in that the Ramadan and Morsel (Nahrung/Food 2002) reference fails to disclose or suggest necessary elements of the claimed invention, Applicant submits that the Examiner's suggestion of anticipation is in error. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejection of claims 1, 2, 3, 23, and 24 under 35 U.S.C. § 102(b) as being anticipated by Ramadan and Morsel (Nahrung/Food 2002).

To further expedite prosecution, Applicant have herewith amended claim 1 to specify that the *Nigella sativa* L. lipid fraction component of the claimed composition comprises "about 73 to about 92% by weight polyunsaturated fatty acids" and further comprises "an oil that is free of solid fats". Applicant respectfully submits that such a composition, "formulated for topical administration to a patient in need thereof", is neither disclosed nor suggested by the prior art of record. Accordingly, Applicant submits that claims 1-5 and 20-24 as amended herein are in condition for allowance and respectfully petition for an early notice of allowance.

Rejections under Section 103 - Kandil in view of Ramadan and Morsel:

Claims 1-5 and 20-22 stand rejected under 35 U.S.C. § 103(a) as being obvious over Kandil (US 2002/0132019 A1) in view of Ramadan and Morsel (Nahrung/Food 2002). The Examiner, citing to Figure 1, asserts that Kandil discloses an oily extract of *N. sativa* identical to that described and claimed by Applicant. However, the Examiner admits that the Kandil reference fails to specifically teach the combination of the composition with a pharmaceutical carrier. To cure this deficiency, the Examiner cites to Ramadan and Morsel (Nahrung/Food 2002) discussed in detail above. The Examiner thus concludes that one skilled in the art would have been motivated to formulate the Figure 1 composition of Kandil (2002) with a pharmaceutical carrier in order to ease the administration of the composition or, alternatively, to dilute the oil for further toxicity testing.

Applicants respectfully disagree.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). See M.P.E.P. § 2142, 2143.

Importantly, the initial burden is on the examiner to provide some suggestion of the desirability of doing what the inventor has done. "To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985). The mere fact that a reference can be modified does not render the resulting modification "obvious" unless the prior art also suggests the desirability of the modification. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). Similarly, although a prior art device "may be capable of being modified to run the way the apparatus is

claimed, there must be a suggestion or motivation in the reference to do so." 916 F.2d at 682, 16 USPQ2d at 1432. In other words, a statement that modifications of the prior art to meet the claimed invention would have been "well within the ordinary skill of the art at the time the claimed invention was made" is not sufficient to establish a *prima facie* case of obviousness without some objective reason to modify or combine the teachings of the reference(s). *Ex parte Levengood, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993). See also In re Kotzab, 217 F.3d 1365, 1371, 55 USPQ2d 1313, 1318 (Fed. Cir. 2000)*

In this case, neither Kandil (2002) nor Ramadan and Morsel (Nahrung/Food 2002) disclose or suggest a composition formulated for topical administration comprised of the claimed *Nigella sativa* lipid fraction and a pharmaceutical carrier. As the Examiner correctly notes, Kandil (2002) provides no suggestion of formulating the disclosed lipid fraction with a pharmaceutical carrier. In fact, as noted previously, Kandil (2002) fails to disclose or suggest any pharmaceutical use, much less a topical use, for the "lipid (oily) fraction". Rather, the only utility afforded to the disclosed oily lipid fraction is as an intermediate in a process for producing a desired final product, namely an unsaponified fraction composed of total sterols and volatile oils. Accordingly, there is no teaching or suggestion in Kandil (2002) to isolate the lipid intermediate and formulate it for topical administration, for example, as "an ointment, cream, gel, powder, balm, lotion, liquid, spray, or aerosol or as the active ingredient in a transdermal patch" as specified in claim 2.

Furthermore, as discussed in detail above and contrary to the Examiner's suggestion, the Ramadan and Morsel (Nahrung/Food 2002) reference includes no suggestion of pharmaceutical compositions formulated for topical administration. Accordingly, in that the cited prior art references when combined fail to teach or suggest all the claim limitations, they cannot serve to establish the *prima facie* obviousness of the presently claimed invention.

Applicant further disagrees with the Examiner's assertion that Kandil (2002) discloses an oily extract of *N. sativa* identical to that described and claimed by Applicant. Applicant respectfully submits that it is the Examiner and not Applicant who misquotes the instant specification and, as such, continues with her mistaken characterization of the respective disclosures. In an effort to clear up the confusion, Applicant directs the Examiner's attention to paragraph [0049] of the Kandil (2002) publication reiterated below:

> "[0049] Nigella sativa L. seeds were crushed and extracted in a percolator until exhaustion with petroleum ether (40 to 60 °C) **or** hexane. The petroleum ether **or** hexane extract was evaporated under reduced pressure at 40 °C and the residue was kept in the refrigerator. The saturated fatty acid fractions and waxes solidified upon cooling and were separated by filtration or decantation." (US 2002/0132019, paragraph [0049], emphasis added)

Accordingly, Kandil (2002) clearly discloses alternative, single solvent extractions. Conversely, the instant application discloses successive, multi-solvent extractions, namely serial extractions with various solvents in order of increasing polarity. In support of this assertion, Applicant directs the Examiner's attention to paragraph [0054] of the instant application as published, reiterated below:

> "[0054] 4 kilograms of crushed Nigella sativa L seeds were successively extracted in a percolator until exhaustion with various solvents in order of increasing polarity. The solvents used, in order, were petroleum ether (with boiling point between 40 - 60 °C) **or** hexane, ether, chloroform, ethylacetate, acetone, ethanol, methanol, **and** water." (US 2005/02114393, paragraph [0054], emphasis added)

Accordingly, as noted herein and previously, the lipid fraction of the instant composition clearly results from a series of extractions, first with either PE or hexane, and subsequently with "ether, chloroform, ethylacetate, acetone, ethanol, methanol, **and** water". Reference to the "intermediate product" in the subsequent paragraph as "the petroleum ether extract" is merely illustrative shorthand (as denoted by the precursor "e.g.") and does not directly negate Applicant's express statement that the lipid fraction of the instant invention arises from multi-solvent extractions rather than a single solvent extraction. In that different solvents are capable of liberating different constituents, Applicant respectfully submits that the lipid fraction of the instant invention will necessarily differ from the lipid fraction obtained by the Kandil (2002) process. Moreover, as noted in the previous response, the distinct extraction process of the instant invention yields an extract with unique properties, namely an *N. sativa* L. oil having a high content of polyunsaturated fatty acids, more particularly linoleic and oleic acids Accordingly, given that the *N. sativa* L. lipid fraction of the instant invention is

unexpectedly and fundamentally different from the intermediate lipid fraction described in the Kandil (2002) publication, Applicant submits that Kandil (2002) cannot be considered to be an enabling disclosure of the lipid fraction now claimed nor can it serve to anticipate or render obvious the invention of the pending claims. Thus, Applicant respectfully submits that one skilled in the art would not expect a "petroleum ether or hexane extract" (as described in Kandil (2002)) to be identical to a composition extracted with 8 separate solvents, in order of increasing polarity.

For the reason set forth above, Applicant respectfully requests reconsideration and withdrawal of the rejection of claims 1-5 and 20-22 under 35 U.S.C. § 103(a) as being obvious over Kandil (2002) in view of Ramadan and Morsel (Nahrung/Food 2002).

CONCLUSION

In sum, Applicant submits that the claims herein set forth a novel, non-obvious invention. Accordingly, Applicant submits that claims 1-5 and 20-24 as amended herein are in condition for allowance and respectfully petition for an early notice of allowance.

The outstanding Office Action set a three-month shortened statutory period for response. Applicant submits herewith a Petition for a Three-Month Extension of Time, extending the deadline for response to on or before **July 26, 2007**. Accordingly, Applicant submits that this response is timely and no additional fee is required. However, in the event that further fees are required to enter the instant response and/or maintain the pendency of this application, the Commissioner is authorized to charge such fees to our Deposit Account No. **50-2101**. If the Examiner has any questions or concerns regarding this communication, she is invited to contact the undersigned.

Respectfully submitted,
By /chalin a. smith/

Date: July 25, 2007

Smith Patent Consulting, LLC
3309 Duke Street
Alexandria, VA 22314
Telephone: (703) 549-7691
Facsimile: (703) 549-7692

Chalin A. Smith
Attorney for Applicant
Registration No. 41,569

CUSTOMER NUMBER: 31496